August 23, 1999

Dockets Management Branch
HFA-305
Food. and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket Number 99D-1878, Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Prior Collections from Donors with Repeatedly Reactive Screening Tests for Hepatitis C Virus (HCV); (2) Supplemental Testing, and the Notification of Consignees and Transfusion Recipients of Donor Test Results for Antibody to HCV (Anti-HCV)

To Whom It May Concern:

On behalf of our nearly 5,000 hospital, health system and network members; the American Hospital Association (AHA) is pleased to submit written comments on the revised Hepatitis C Virus (HCV) lookback.

The guidance would require blood banks, to notify hospitals that have been supplied with blood units potentially contaminated by the hepatitis C virus. Hospitals would..then. attempt to notify recipients of these blood products and inform them of the need for HCV testing and counseling.

Consistent with our previous comments to the Food and Drug Administration (FDA) on this issue, the AHA supports the general thrust of the underlying guidance. We recognize the impact this lookback will have on patients who may be HCV-infected as a result of a blood transfusion. However, we suggest the following modifications to the revised guidance.

The document, which replaces the September 23, 1998, HCV lookback guidance, incorporates new recommendations for conducting lookback on donations by individuals who test positive on first generation HCV tests (HCV EIA 1 .O). We are concerned that any expansion of the current HCV lookback is premature and should be postponed until the FDA, in conjunction with the, Centers for Disease Control and Prevention (CDC), can evaluate the results of the current lookback.

In talking with two of our member hospitals about their experience with the current HCV lookback, both reported a very small percentage of individuals who have tested positive for HCV. In one hospital, 471 transfusion patients were identified as being potentially"" HCV-positive. Of the 47 1 patients, 315 had died. from non-related medical, conditions.

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Of the 156 remaining transfusion recipients, 23 tested positive both before and after the blood transfusion. In the end, 20 recipients out of 471 were identified as HCV positive. In another hospital, 46 transfusion patients were identified as being potentially HCV-positive. Of these, 18 were deceased, while 14 were notified and told. to be tested. Of these 14, nine elected to be tested elsewhere, Of the five tested at the hospital, three tested positive for HCV,

In addition, we are concerned about the high false-positive rate associated with the HCV EIA 1 .O test. Harvey Alter, MD., Chief of Immunology at the National Institutes of Health, recognized theweakness of this test at a September 13, 1990, meeting of the Michigan Association of Blood Banks, when he acknowledged a 30-70 percent. false-positive rate for the HCV EIA 1.0. In light of the small proportion of blood recipients-who have been identified as being HCV-positive under the HCV EIA 2.0/3.0 tests, combined with the extremely high false-positive rate of the EIA 1.0 test, we believe that it is incumbent upon the FDA and the CDC to evaluate the results of the current lookback and document its benefits before it proceeds with any expansion of the lookback.

Second, the revised guidance includes an indefinite "open-ended" lookback period. FDA now recommends that the search of records of prior donations from donors with repeatedly reactive screening tests for HCV "extend back indefinitely to the extent that electronic or other readily retrievable records exist." We believe that this recommendation is vague and overly broad and could have tremendous legal implications, which might defeat the intended purpose of the lookback. As a result, we recommend that the language be modified by striking "extend back indefinitely" and. simply stating, "The record search should extend back 10 years or, if longer, the minimum time period for medical records retention specified in state law." This way, there is a finite date in place, patients can be notified in as expeditious and organized a manner as possible and additional burdensome requirements on hospitals and blood establishments can be eliminated.

Thank you for the opportunity to share our comments with you. We look forward to working with the FDA to address this critical patient care issue. Should you have any questions regarding our comments, please contact me or Mary Beth Savary Taylor, AHA's director of executive branch relations, at 202-626-2270.

Sincerely,

Rick Pollack

Rick Pollack
Executive Vice President

cc: Robin Biswas, M.D., Laboratory of Hepatitis Chief
Transfusion Transmitted Diseases Division,